

REMARKS

Claims 1-8, 10-11, 13-22, 24-27 and 31-42 are pending after the present amendments. Applicants gratefully acknowledge the Examiner's indication that claims 6-11 and 23 are allowable if rewritten in independent form. Applicants address each rejection, and respectfully request reconsideration in view of the present amendments.

Rejections under 35 U.S.C. §112, first paragraph

Claims 1 and 31-42 were rejected under 35 U.S.C. §112, first paragraph, as allegedly non-enabled. The Office indicated that the specification is enabling for treating colon cancer, but does not reasonably provide enablement for ameliorating or reducing all known cell proliferative disorders and microbial titers. In particular, the Office indicated that there are no working examples showing efficacy of instant compounds in animal models or cell lines of all known cell proliferative disorders or microbial infections. The Office also stated that "in absence of such teachings, guidance and presence of working examples, it would require undue experimentation to demonstrate the efficacy of instant compounds in known animal models or cell lines of every known cell proliferative disorder and microbial infection." (Office Action, pages 3-4). Applicants respectfully disagree.

With regard to claim 1, this rejection is improper as claim 1 is directed only to the inventive compounds, and not to methods of ameliorating or reducing cell proliferative disorders and microbial titers. With regard to claims 31-42, Applicants submit that these claims are also enabling for treating or reducing other cell proliferative disorders and microbial titers. It is well established that compliance with the enablement requirement does not turn on whether an example is disclosed. "The specification need not contain an example if the invention is otherwise disclosed in such manner that one skilled in the art will be able to practice it without an undue amount of experimentation." (See, MPEP 2164.02). As indicated in *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988), "a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in

which the experimentation should proceed.” *In re Wands*, 858 F.2d at 737 (citation omitted). (See also, MPEP § 2164.01(a)).

In the present case, one skilled in the art would be able to readily identify the effect of an effective compound of the instant invention experimentally using cell proliferation assays as described in the specification. (See specification at page 18, ¶ 59). Various commercially available proliferation and microbial assays may also be used to determine the effect of the instant compound on cell proliferation and microbial titers. (See e.g., <http://las.perkinelmer.com/Catalog/default.htm?CategoryID=Cytotoxicity%2FCell+Proliferation+Assays>, attached at Exhibit 1; <http://las.perkinelmer.com/content/ApplicationNotes/12349866-Proliferation.pdf>, attached at Exhibit 2; <http://www.biocompare.com/jump/1201/Cell-ViabilityProliferation-Assays.html>, attached at Exhibit 3; http://www.promega.com/pnotes/88/12162_02/12162_02.pdf (attached at Exhibit 4)). Furthermore, one skilled in the art would know how to determine the amount of compound that will treat a cell proliferative disorder or a microbial infection.

Because the specification provides adequate guidance on how to make and use the present invention, claims 1 and 31-42 are enabled. Applicants therefore respectfully request that this rejection be withdrawn.

Rejection under 35 U.S.C. §112, second paragraph

Claims 1, 12-22, 24, 26, and 31-42 were rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. To expedite prosecution, the claims have been amended to define the variables R^1 and R^2 , and to clarify the value of R^6 . The structures in variable Y have also been amended to conform to the description in the specification that two adjacent R^6 groups can be linked to form a ring. Compounds described in Table 1 have also been incorporated in claim 26. No new matter has been added.

The Office also indicated that claims 12-22 recite a limitation with insufficient antecedent basis. The limitations in previously pending claim 12 have been incorporated in claim 1, rendering this rejection moot.

Furthermore, the Office rejected claim 24 for reciting the term “inorganic substituents.” Applicants respectfully disagree. One of ordinary skill in the art would understand that “inorganic substituents” refer to compounds without any carbons. (See <http://www.google.com/search?hl=en&q=define%3A+inorganic+compound>, attached at Exhibit 5). Thus, the term “inorganic substituents” is clear and definite, and Applicants respectfully request that this rejection be withdrawn.

Further, the Office rejected claims 31-42, for reciting the terms “cell proliferative disorder and microbial infection.” Applicants respectfully disagree. One of ordinary skill in the art would understand that a cell proliferative disorder is a disorder resulting from an increase in cell number as a result of cell growth and division. (See e.g., <http://www.google.com/search?hl=en&lr=&q=define%3A+cell+proliferation>, attached at Exhibit 6). The specification also describes various cell proliferative disorder on page 8, ¶ 31. Microbial infections are also well understood in the art. (See e.g., <http://www.nature.com/nature/insights/6797.html>, attached at Exhibit 7). Accordingly, Applicants respectfully request that this rejection be withdrawn.

The Office also rejected claims 31, 35, 37 and 40 for reciting the terms “ameliorating or reducing,” which are allegedly indefinite since the degree of amelioration or reduction is not defined and the Office questions how amelioration or reduction is being assessed. Applicants respectfully disagree. However, to expedite prosecution, the term “ameliorating” has been amended to “treating,” which is defined in the specification at page 9, ¶ 33. In addition, acceptability of the claim language does not depend on the degree of reduction, and those skilled in the art would be able to determine how the desired treatment or reduction could be effected using the compounds of the present invention. Furthermore, as previously indicated, cell proliferation assays and microbial

assays are known in the art to quantify cell proliferation and microbial titers. Thus, Applicants respectfully request that this rejection be withdrawn.

Finally, the Office indicated that in claims 35 and 37, it is unclear whether the method is in vitro or in vivo. Whether the method is in vitro or in vivo has no bearing on the definiteness of claims 35 and 37, which encompass both methods.

Based on the above, Applicants respectfully submit that these claims are clear and definite, and request that this rejection be withdrawn.

Rejection under 35 U.S.C. §102

Claims 1-5, 25-27, and 31-42 were rejected under 35 U.S.C. §102(b) as allegedly being anticipated by Tomita (JP 09221424). In particular, the Office cites to compound 8F1 on page 22. As amended, R2 is not H, and thus excludes compound 8F1. Applicants therefore respectfully request that this rejection be withdrawn.

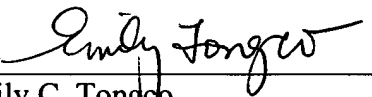
CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. 532232001200. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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